REMARKS

I. Status Summary

Claims 56-61 and 63-92 are pending in the present U.S. patent application and have been examined. An Official Action (hereinafter the "Official Action") was issued May 23, 2005 by the United States Patent and Trademark Office (hereinafter the "Patent Office").

The priority claim has been objected to upon the contention that the priority document, U.S. Patent Application Serial No. 09/152,160 (hereinafter "the '160 Application), now U.S. Patent No. 6,248,327 (hereinafter "the '327 Patent"), does not support the sequence presented in SEQ ID NO: 1.

Claims 74, 75, 80, and 89 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the specification does not satisfy the rules governing the deposit of biological material as set forth in M.P.E.P. 2408 and 37 C.F.R. § 1.806.

Claims 56, 58-59, 63, 65, 67-69, 71, 73-77, 79-80, 82-84, 86, and 88-92 have been rejected under 35 U.S.C. § 102(a) upon the contention that the claims are anticipated by Takahashi *et al.* (1999) J Am Soc Nephrol 10:2135-2145; hereinafter "Takahashi").

Claims 63, 67, 83, 84, and 92 have been rejected under 35 U.S.C. § 102(b) upon the contention that the claims are anticipated by Honda *et al.* (1994) Blood 81:4186-94 (hereinafter "Honda").

Claims 56-58, 60, 68-73, 76-79, 81-82, and 90-91 have been rejected under 35 U.S.C. § 103(a) upon the contention that the claims are unpatentable over Honda in view of Tonks *et al.* (WO 95/30008; hereinafter "Tonks"). Claims 56-60 and 63-92 have also been rejected under this section upon the contention that the claims are obvious over Takahashi in view of Tonks.

The Patent Office has indicated that claim 60 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. It would appear, however, that it is claim 61 that would be so allowable, since there are no

current rejections pending against claim 61, but there are rejections pending against claim 60. *See also* PTOL-326 form provided with the instant Official Action.

Claims 56-60, 63-67, 73, 82, 88, and 90-92 have been canceled without prejudice. Applicants respectfully reserve the right to file one or more continuing patent applications containing claims directed to the subject matter encompassed by claims 56-61, 63-67, 73, 82, 88, and 90-92.

Claims 61, 68-72, 74-81, and 83-87 have been amended. The amendment to claim 61 is solely to re-write claim 61 as an independent claim reciting the elements of the claims from which it ultimately depends (*i.e.*, claim 56). Support for the amendments to claims 68-72, 74-81, and 83-87 can be found throughout the specification as filed, including particularly at page 28, lines 3-6 (administration of a composition comprising a therapeutically effective amount of an ECRTP/DEP-1 modulator capable of binding the ECRTP/DEP-1). Additional support for the amendments can be found at page 25, lines 13-17 (treatment of humans), at page 32, lines 11-16 (pharmaceutically acceptable diluents and excipients), at page 52, lines 1-4 (inhibition of angiogenesis), SEQ ID NOs: 1 and 4 (SEQ ID NO: 1 is amino acid 324-331 of SEQ ID NO: 4), and claim 1 as originally filed (antibody fragments and derivatives). Thus, no new matter has been added by any of the amendments.

New claims 93-97 have been added. New claims 93 and 94 depend directly or indirectly from, or are based on, claim 61, and recite the elements of claims 58 and 60 from which claim 61 had depended in addition to claim 56. New claim 95 recites a composition comprising a therapeutically effective amount of the isolated antibody, or the fragment or derivative thereof, of claim 61, in conjunction with a diluent or excipient pharmaceutically acceptable in humans. The elements of claim 61 have been incorporated directly into the claim as opposed to being incorporated by reference to claim 61. Claims 96 and 97 depend from claim 95, and include the elements of claims 58 and 60. Thus, support for the new claims can be found throughout the specification as filed, including particularly in claims 58, 60, and 61. Accordingly, applicants respectfully submit that no new matter has been added by the addition of new claims 93-97.

Reconsideration of the application as amended and based on the arguments set forth herein below is respectfully requested.

II. Response to the Objection to the Priority Claim

The Patent Office asserts that the '160 Application does not support the disclosure of SEQ ID NO: 1, and thus has contended that the filing date of the instant application (*i.e.*, March 1, 2000) is to be used for the determination of prior art.

After careful consideration of the objection and the Patent Office's bases therefor, applicants respectfully traverse the objection and submit the following remarks.

Applicants respectfully submit that with respect to continuation applications, the child is entitled to the filing date of the parent for all claims for which support can be found in the parent. Applicants further respectfully submit that that this rule applies also to continuations-in-part such as the instant U.S. Patent Application Serial No. 09/516,728. Accordingly, applicants respectfully submit that for all claims that find support in the priority document of the instant application (*i.e.*, in the '160 Application as originally filed), the correct priority date is September 11, 1998, the filing date of the '160 Application.

Applicants respectfully submit that the '160 Application discloses monoclonal antibody (Mab) ECRTPAb-1, having molecular weight of about 150 KDa and which binds to the ectodomain of the ECRTP/DEP-1 receptor. The '160 Application further discloses hybridoma cell line ATCC HB12570 and that hybridoma cell line ATCC HB12570 was deposited pursuant to Budapest Treaty requirements with the American Type Culture Collection (ATCC), Manassas, VA, U.S.A. on September 18, 1998.

Furthermore, the Patent Office has rejected claims 56, 58-59, 63, 65, 67-69, 71, 73-77, 79-80, 82-84, 86, and 88-92 under 35 U.S.C. § 102(a) upon the contention that the claims are anticipated by Takahashi. In order to support the rejection of these claims over Takahashi, the Patent Office must contend that Takahashi discloses each and every element of claims 56, 58-59, 63, 65, 67-69, 71, 73-77, 79-80, 82-84, 86, and 88-92. Thus, it would appear that the Patent Office is asserting that the disclosure of monoclonal antibody ECRTP.Ab1 in Takahashi explicitly or implicitly discloses each and

every element of claims 56, 58-59, 63, 65, 67-69, 71, 73-77, 79-80, 82-84, 86, and 88-92. Applicants respectfully note, however, that monoclonal antibody ECRTP.Ab1 was disclosed in the priority document of the instant application, *i.e.*, the '160 Application. The Patent Office's attention is directed to Figures 1-4 and 8-10, column 8, lines 51-54, column 18, lines 42-56, and column 20, lines 19-28, of the '327 Patent. Applicants respectfully submit that these sections disclose monoclonal antibody ECRTP.Ab1 and the deposit of hybridoma cell line ATCC HB12570 with the American Type Culture Collection of Manassas, Virginia, under the terms of the Budapest Treaty.

Thus, applicants respectfully submit that if the disclosure of Takahashi would otherwise support the rejection under 35 U.S.C. § 102(a) presented in the currently pending Official Action, the disclosure of ECRTP.Ab1 in the '160 Application also supports applicants' claim to priority to the filing date of that document. Stated another way, applicants respectfully submit that the disclosure of monoclonal antibody ECRTP.Ab1 in the '160 Application is sufficient to support applicants' claim to priority to the '160 Application for all that the '160 Application discloses.

Additionally, applicants respectfully note that Takahashi was published in the October 1999 issue of the *Journal of the American Society of Nephrology*. The filing date of the '160 Application is September 11, 1998. Thus, applicants respectfully submit that the correct priority date of the instant application, particularly with respect to claims 56, 58-59, 63, 65, 67-69, 71, 73-77, 79-80, 82-84, 86, and 88-92, is September 11, 1998, prior to the publication date of Takahashi. Thus, and for the reasons set forth in more detail hereinbelow, Takahashi does not qualify as prior art under § 102(a).

Accordingly, applicants respectfully submit that the Patent Office's assignment of March 1, 2000 as the priority date of the instant application is incorrect, and the actual priority date should be September 11, 1998, at least with respect to claims 56, 58-59, 63, 65, 67-69, 71, 73-77, 79-80, 82-84, 86, and 88-92. Applicants therefore respectfully request that the instant objection to the priority claim be withdrawn.

III. Response to the Rejection Based on 35 U.S.C. § 112, First Paragraph

Claims 74, 75, 80, and 89 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the claims do not comply with the enablement requirement set forth therein. According to the Patent Office, the specification does not comply with M.P.E.P. 2408 and/or 37 C.F.R. § 1.806 with respect to the deposit (*i.e.*, the deposit of hybridoma cell line ATCC HB12570).

After careful consideration of the rejection and the Patent Office's bases therefor, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants respectfully submit that the Patent Office has not indicated how the disclosure of the specification is deficient with respect to M.P.E.P. 2408 and/or 37 C.F.R. 1.806. M.P.E.P. 2408 states the following:

> The term of deposit must satisfy the requirements of the Budapest Treaty which sets a term of at least 30 years from the date of deposit and at least 5 years after the most recent request for the furnishing of a sample of the deposit was received by the depository. In the event that the 30-year term covers the 17-year term or 20-year term of the patent plus 6 years to include the Statute of Limitations, no further requirement is necessary. Unless applicant indicates that the deposit has been made under the Budapest Treaty, applicant must indicate the term for which the deposit has been made. The mere possibility of patent term extension or extended litigation involving the patent should not be considered in this analysis.
>
> In the event that the 30-year term of deposit measured from the date of deposit would necessarily terminate within the period of enforceability of the patent (the normal 17-year term or 20-year term plus 6 years to include the Statute of Limitations), samples must be stored under agreements that would make them available beyond the enforceable life of the patent (i.e., until 23 years after issuance or 26 years after application filing) for which the deposit was made. No requirement should be made as to any particular period of time beyond the enforceable life of the patent. The purpose of the requirement is to insure that a deposited biological material necessary for the practice of a patented invention would be available to the public after expiration of the patent for which the deposit was made. The term of the deposit must comply with the requirements of each sentence of 37 CFR 1.806 whether or not the deposit is made under the Budapest Treaty. A specific statement that the deposit complies with the second sentence of this section is required only

> where the 30-year term would terminate within the enforceable life of the patent.

M.P.E.P. 2408 (emphasis added).

Applicants respectfully submit that the plain language of M.P.E.P. 2408 clearly indicates that "Unless applicant indicates that the deposit has been made under the Budapest Treaty, applicant must indicate the term for which the deposit has been made" (emphasis added). Thus, applicants respectfully submit that only in the event that the specification does not state that the deposit was made under the terms of the Budapest Treaty must the terms under which the deposit has been made be specifically defined.

Applicants direct the Patent Office's attention to page 42, lines 17-20, of the instant specification. These lines explicitly state: "The hybridoma cell line ATCC HB12570 was deposited pursuant to Budapest Treaty requirements with the American Type Culture Collection (ATCC), 10801 University Boulevard, Manassas, Virginia, 20110-2209, U.S.A., on September 18, 1998" (emphasis added). Thus, applicants respectfully submit that the deposit was with a public depository under the terms of the Budapest Treaty (*i.e.*, for a term of at least thirty years and at least five years after the most recent request for the furnishing of a sample of the deposit was received by the depository), and thus complies with the requirements of M.P.E.P. 2408.

The Patent Office's attention is also directed to U.S. Patent Nos. 6,953,847; 6,953,690; and 6,953,668; each of which issued October 11, 2005. These patents disclose simply that the relevant deposits were made pursuant the to the Budapest Treaty, the name of the depository, the date of deposit, and the relevant Accession numbers. Thus, applicants respectfully submit that the instant specification complies with the disclosure requirements of M.P.E.P. 2408.

Furthermore, applicants respectfully submit that the deposit complies with the requirements of 37 C.F.R. §1.806, which states:

> A deposit made before or during pendency of an application for patent shall be made for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposit was received by the depository. In any case, samples must be

> stored under agreements that would make them available beyond the enforceable life of the patent for which the deposit was made.

Applicants respectfully submit that these requirements are identical to the terms of the Budapest Treaty, which according to M.P.E.P. 2408 "sets a term of at least 30 years from the date of deposit and at least 5 years after the most recent request for the furnishing of a sample of the deposit was received by the depository". Thus, applicants respectfully submit that the deposit clearly also satisfies the requirements of 37 C.F.R. § 1.806.

Continuing with the instant rejection, M.P.E.P. 2408 also states:

> The term of the deposit must comply with the requirements of each sentence of 37 CFR 1.806 whether or not the deposit is made under the Budapest Treaty. A specific statement that the deposit complies with the second sentence of this section is required only where the 30-year term would terminate within the enforceable life of the patent.

M.P.E.P. 2408 (emphasis added). As such, applicants respectfully submit that only if the 30-year term would terminate within the enforceable life of the patent would additional disclosure be necessary. With reference to the instant specification, applicants respectfully submit that the deposit was made on September 18, 1998. The 30-year term or the deposit would thus expire no earlier than September 18, 2028. The enforceable life of a patent that issues from the instant application is maximally March 1, 2026 (20 years from the earliest non-provisional priority date claimed plus six years to include the Statute of Limitations as per M.P.E.P. 2408), or as applicants have claimed a priority date of September 11, 1998, September 11, 2024.

And finally, applicants respectfully submit that according to M.P.E.P. 2410.01, "the mere indication that a deposit has been made under conditions prescribed by the Budapest Treaty would satisfy all conditions of these regulations except the requirement that all restrictions on access be removed on grant of the patent". As to this final condition, applicants herein confirm that the deposit was made with the stipulation that all restrictions on access are to be irrevocably removed on grant of a patent. Applicants further respectfully submit that the deposit was made in connection with the filing of the

'160 Application, which has issued as U.S. Patent No. 6,248,327. Thus, all restrictions on access to ATCC HB12570 have already been irrevocably removed.

Thus, applicants respectfully submit that the 30-year term of the deposit cannot expire within the enforceable life of the patent, and thus applicants respectfully submit that the specification satisfies the enablement requirement of 35 U.S.C. § 112, first paragraph. Accordingly, applicants respectfully submit that the instant rejection of claims 74, 75, 80, and 89 under 35 U.S.C. § 112, first paragraph, is improper, and respectfully submit that it be withdrawn at this time.

IV. Response to the Rejection under § 102(a)

Claims 56, 58-59, 63, 65, 67-69, 71, 73-77, 79-80, 82-84, 86, and 88-92 have been rejected under 35 U.S.C. § 102(a) upon the contention that the claims are anticipated by Takahashi. According to the Patent Office, Takahashi discloses monoclonal antibody (Mab) ECRTP.Ab1.

After careful consideration of the rejection and the Patent Office's bases therefor, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants respectfully direct the Patent Office's attention to the remarks presented hereinabove in Section II. Particularly, applicants respectfully submit that Takahashi was published in the October 1999 issue of the Journal of the American Society of Nephrology. Applicants contend that the correct priority date of the instant application, particularly with respect to claims 56, 58-59, 63, 65, 67-69, 71, 73-77, 79-80, 82-84, 86, and 88-92, is September 11, 1998. Thus, Takahashi does not qualify as prior art under § 102(a), and as such, applicants respectfully request that the instant rejection be withdrawn at this time.

Accordingly, applicants respectfully request that the instant rejection of claims 56, 58-59, 63, 65, 67-69, 71, 73-77, 79-80, 82-84, 86, and 88-92 be withdrawn at this time. Claims 56, 58-59, 63, 65, 67, 73, 82, 88, and 90-92 have been canceled herein, and thus applicants respectfully submit that the instant rejection is thus believed to be moot as to these claims. Accordingly, applicants respectfully submit that claims 68, 69, 71,

74-77, 79, 80, 83, 84, and 89 are in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

V. Response to the Rejection under § 102(b)

Claims 63, 67, 83, 84, and 92 have been rejected under 35 U.S.C. § 102(b) upon the contention that the claims are anticipated by Honda. According to the Patent Office, Honda teaches an antibody derived from rabbit serum, which qualifies as a pharmaceutically acceptable carrier.

After careful consideration of the rejection and the Patent Office's bases therefor, applicants respectfully traverse the rejection and submit the following remarks.

Initially, applicants respectfully submit that claims 63, 67, and 92 have been canceled, and thus the instant rejection is believed to be moot as to these claims. Applicants will thus address the instant rejection as applied to claims 83 and 84.

Continuing with the instant rejection, applicants respectfully submit that claims 83 and 84 recite *inter alia* compositions comprising a therapeutically effective amount of an isolated antibody, or a fragment or derivative thereof, which specifically binds to an epitope present within amino acids 324-331 of a human ECRTP/DEP-1 density enhanced phosphatase-1 polypeptide comprising an amino acid sequence as set forth in SEQ ID NO: 4, in a diluent or excipient pharmaceutically acceptable for use in humans, wherein the composition inhibits angiogenesis. The Patent Office asserts in support of the instant rejection that rabbit serum "qualifies as a pharmaceutically acceptable carrier" (*see* Official Action at page 6). Applicants respectfully submit, however, that the claims recite that the antibodies are present in a diluent or excipient pharmaceutically acceptable for use in humans, and rabbit serum does not qualify as a pharmaceutically acceptable diluent or excipient for use in humans. The Patent Office has provided no reference or other scientifically reasonable evidence that supports the assertion that rabbit serum is pharmaceutically acceptable for administration to humans. Applicants thus respectfully submit that the Patent Office has not satisfied its burden of establishing a *prima facie* case of anticipation under § 102(b) because the cited Honda reference does not disclose every element of claims 83 and 84.

Furthermore, applicants respectfully submit that claim 83 explicitly recites that the antibody, the fragment or derivative thereof, binds to an epitope present within amino acids 324-331 (*i.e.*, corresponding to SEQ ID NO: 1). Applicants respectfully submit that Honda does not disclose an antibody, fragment, or derivative thereof that binds to this epitope.

And finally, applicants respectfully submit that the compositions of claims 83 and 84 comprise *inter alia* isolated antibodies, or fragments or derivatives thereof, which inhibit angiogenesis. Applicants respectfully submit that Honda does not and indeed, cannot be interpreted to teach or disclose antibodies that inhibit angiogenesis.

Accordingly, applicants respectfully submit that the instant rejection of claim 83 under 35 U.S.C. § 102(b) over Honda is improper, and respectfully request that it be withdrawn at this time. Applicants further respectfully submit that claim 84 depends from distinguished claim 83, and thus are also believed to be distinguished from the cited Honda reference. Thus, applicants respectfully submit that claims 83 and 84 are in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

VI. Response to the Rejections Based on 35 U.S.C. § 103(a)

Claims 56-58, 60, 68-73, 76-79, 81-82, and 90-91 have been rejected under 35 U.S.C. § 103(a) upon the contention that the claims are unpatentable over Honda in view of Tonks. Claims 56-60 and 63-92 have also been rejected under this section upon the contention that the claims are obvious over Takahashi in view of Tonks.

After careful consideration of the rejections and the Patent Office's bases therefor, applicants respectfully traverse the rejections and submit the following remarks.

Initially, applicants respectfully submit that claims 56-58, 60, 73, 82, 90, and 91 have been canceled, and thus the instant rejection is believed to be moot as to these claims. Applicants will thus address the instant rejection as applied to claims 68-72, 76-79, and 81.

VI.A. Response to the Rejection over Takahashi in view of Tonks

According to the Patent Office, Takahashi discloses the subject matter of claims 56, 58, 59, 63, 65, 67-69, 71, 73-77, 79, 80, 82-84, 86, and 88-92. The Patent Office concedes, however, that Takahashi does not disclose antibody fragments that bind to an epitope present within amino acids 175-536 of ECRTP/DEP-1, nor does it teach human or humanized antibodies. The deficiency is asserted to be cured by Tonks, which the Patent Office contends teaches fragments such as scFv and chimeric antibodies. The Patent Office thus asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct fragments of ECRTPAb.1, and that the skilled artisan would be motivated to do so because Takahashi taught that ECRTPAb-1 was effective at recognizing ECRTP/DEP-1 and Tonks taught that antibody fragments directed to ECRTP/DEP-1 could be made and were in fact effective at modulating ECRTP/DEP-1 activity *in vivo* and/or that Tonks taught that antibodies against ECRTP/DEP-1 have a useful function *in vivo*.

Initially, applicants respectfully submit that Takahashi has been excluded as prior art, and thus the combination of Takahashi and Tonks is improper. Accordingly, applicants respectfully request that the instant rejection of claims 68-72, 76-79, and 81 under 35 U.S.C. § 103(a) over Takahashi in view of Tonks be withdrawn at this time.

VI.B. Response to the Rejection over Honda in view of Tonks

Claims 68-72, 76-79, and 81 have also been rejected under 35 U.S.C. § 103(a) upon the contention that the claims are unpatentable over Honda in view of Tonks. According to the Patent Office, Tonks teaches antibodies to DEP-1, and that these antibodies are used for "modulating... the *in vivo* binding and/or signal transduction activities of Type III density enhanced phosphatases". While the Official Action does not indicate what contribution Honda makes to the asserted *prima facie* case, applicants assume that Honda is being relied on for its asserted disclosure of anti-DEP-1 antibodies in rabbit serum.

In order to support a *prima facie* case of obviousness under § 103, the cited references must disclose or suggest all the claim elements. Applicants respectfully submit that the combination of Honda and Tonks fails to disclose or suggest all the

elements of the currently claimed subject matter. Particularly, the cited combination does not teach or suggest a composition comprising an antibody, or a fragment or derivative thereof, which specifically binds an extracellular domain (claim 68 and dependents thereof), and/or an epitope present within amino acids 175-538 of SEQ ID NO: 4 (claims 76 and dependents thereof), in a diluent or excipient pharmaceutically acceptable in humans, that inhibits angiogenesis. As discussed in more detail hereinabove, Honda does not disclose or suggest antibodies provided in such a diluent or excipient. Neither does Tonks disclose or suggest this element.

Furthermore, applicants respectfully submit that neither Honda nor Tonks discloses that ECRTP/DEP-1 has any activity in modulating angiogenesis. Thus, applicants respectfully submit that the cited combination cannot be read to disclose or suggest compositions that have angiogenesis-inhibiting activity as recited in the instant claims.

The Patent Office asserts that the since the instant claims are directed to products *per se*, the antibodies of Honda and Tonks would have the required activity. Applicants respectfully disagree. The instant rejection is based on 35 U.S.C. § 103(a), and thus the combination must provide a suggestion to modify the references to arrive at the claimed antibodies, must disclose or suggest each and every element of the claimed antibodies, and must provide the skilled artisan with a reasonable expectation of successfully creating the claimed antibodies. Applicants respectfully submit that the Patent Office's reliance on the assertion that the antibodies would inherently contain angiogenesis-inhibiting activity is an example of an impermissible hindsight reconstruction of the references that if permitted, would obviate the requirement that the prior art contain the teaching or suggestion to combine the references. As the Court of Appeal for the Federal Circuit stated in In re Rijckaert, 9 F.3d 1531, 1534, 13 USPQ2d 1248, 1250 (Fed. Cir. 1989), "[s]uch a retrospective view of inherency is not a substitute for some teachings or suggestion supporting an obviousness rejection" (*citing* In re Newell, 891 F.2d 899, 901, 13 USPQ2d 1248, 1250 (Fed. Cir. 1989)).

Thus, and contrary to the Patent Office's assertions on page 7 of the Official Action, the burden is not on applicants to "prove that the claimed product is different

from those taught by the prior art and to establish patentable differences" because, as stated in In re Rijckaert, "the burden to rebut a rejection for obviousness does not arise until a *prima facie* case has been established" (9 F.3d at 1534). Accordingly, since the cited combination of references does not disclose or suggest each and every element in the claimed subject matter and there is no motivation to combine the references as suggested by the Patent Office without the benefit of hindsight, applicants respectfully submit that the cited combination does not support a *prima facie* case of obviousness of claims 68-72, 76-79, and 81 under § 103 (*see also* M.P.E.P. § 2143.03). Thus, applicants respectfully submit that the instant rejection under § 103 is improper, and respectfully request that the rejection of claims 68-72, 76-79, and 81 under 35 U.S.C. § 103(a) be withdrawn. Applicants further respectfully request that the claims be allowed at this time.

VII. Discussion of the New Claims

New claims 93-97 have been added. New claims 93 and 94 depend directly or indirectly from claim 61, and recite the elements of claims 58 and 60 from which claim 61 had depended in addition to claim 56. New claim 95 recites a composition comprising a therapeutically effective amount of the isolated antibody, or the fragment or derivative thereof, of claim 61, in conjunction with a diluent or excipient pharmaceutically acceptable in humans. The elements of claim 61 have been incorporated directly into the claim as opposed to being incorporated by reference to claim 61. Claims 96 and 97 depend from claim 95, and include the elements of claims 58 and 60. Thus, support for the new claims can be found throughout the specification as filed, including particularly in claims 58, 60, and 61. Accordingly, applicants respectfully submit that no new matter has been added by the addition of new claims 93-97.

Applicants respectfully submit that new claims 93-97 are believed to be free from the art based upon their dependency from claim 61, which the Patent Office has indicated is free of the art. Accordingly, applicants respectfully submit that claims 93-97

are in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

CONCLUSIONS

In light of the above Amendments and the Remarks presented hereinabove, it is respectfully submitted that claims 56-61 and 63-92 are in proper condition for allowance, and such action is earnestly solicited.

If any minor issues should remain outstanding after the Examiner has had an opportunity to study the Amendment and Remarks, it is respectfully requested that the Examiner telephone the undersigned attorney so that all such matters may be resolved and the application placed in condition for allowance without the necessity for another Action and/or Amendment.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any deficiencies or credit any overpayments associated with the filing of this correspondence to Deposit Account Number **50-0426**.

Respectfully submitted,
JENKINS, WILSON & TAYLOR, P.A.

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